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# Pre-implantation implantable cardioverter defibrillator concerns and Type D personality increase the risk of mortality in patients with an implantable cardioverter defibrillator

Susanne S. Pedersen<sup>1,2\*</sup>, Krista C. van den Broek<sup>1</sup>, Ruud A.M. Erdman<sup>2</sup>, Luc Jordaens<sup>2</sup>, and Dominic A.M.J. Theuns<sup>2</sup>

<sup>1</sup>CoRPS—Center of Research on Psychology in Somatic diseases, Department of Medical Psychology, Room P506, Tilburg University, Warandelaan 2, PO Box 90153, 5000 LE Tilburg, The Netherlands; and <sup>2</sup>Department of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands

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## Aims

Little is known about the influence of psychological factors on prognosis in implantable cardioverter defibrillator (ICD) patients. We examined the influence of the *distressed* personality (Type D) and pre-implantation device concerns on short-term mortality in ICD patients.

## Methods and results

Consecutively implanted ICD patients ( $N = 371$ ; 79.5% men) completed the Type D Scale and the ICD Patient Concerns questionnaire prior to implantation and were followed up for short-term mortality. The prevalence of Type D was 22.4%, whereas 34.2% had high levels of ICD concerns. The incidence of mortality was higher in Type D vs. non-Type D patients [13.3% vs. 4.92%; hazard ratio (HR): 2.74; 95% confidence interval (CI): 1.24–6.03] and in patients with high vs. low levels of ICD concerns (11.0% vs. 4.5%; HR: 2.38; 95% CI: 1.08–5.23). Type D personality (HR: 2.79; 95% CI: 1.25–6.21) and high levels of ICD concerns (HR: 2.38; 95% CI: 1.06–5.34) remained independent predictors of mortality in separate analyses, adjusting for sex, age, ICD indication, coronary artery disease, and shocks. Patients with clustering of both Type D personality and high levels of pre-implantation concerns (HR: 3.86; 95% CI: 1.64–9.10) had a poorer survival compared with patients with one or none of these risk markers in adjusted analysis. Shocks during the follow-up period were also associated with mortality (HR: 3.09; 95% CI: 1.36–7.04).

## Conclusion

Patients with a distressed personality and high levels of pre-implantation device-related concerns had a poorer prognosis, independent of other risk markers including shocks. This subgroup of patients should be identified in clinical practice and would likely benefit from a combined distress management programme and cardiac rehabilitation.

## Keywords

Type D personality • Device-related concerns • Implantable cardioverter defibrillator • Mortality • Shocks

## Introduction

The implantable cardioverter defibrillator (ICD) has evolved to therapy of first choice for the treatment of life-threatening arrhythmias both as primary and secondary prophylaxis.<sup>1–3</sup> Despite the proven medical benefits of ICD therapy, there is an ongoing debate as to which criteria to use for risk stratification to identify patients at high risk for sudden cardiac death (SCD).<sup>4</sup> Impaired ejection fraction, microvolt T-wave alternans, and markers of autonomic nervous system functioning, such as heart rate variability and

baroreflex sensitivity, are some of the candidates that have been examined. However, SCD is not likely to be the end product of one mechanism but more likely attributable to a range of processes, necessitating the use of multivariable risk modelling and complex algorithms.<sup>4</sup> Psychological factors might also have a place in such algorithms, provided that they have an independent prognostic value from standard risk markers.

A growing body of evidence suggests that psychological factors, including anxiety,<sup>5</sup> anger,<sup>6</sup> anger-induced T-wave alternans,<sup>7</sup> and depression,<sup>8</sup> may influence the onset of ventricular arrhythmias

\* Corresponding author. Tel: +31 13 466 2503; fax: +31 13 466 2370, Email: s.s.pedersen@uvt.nl

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in ICD patients. A recent study demonstrated that the clustering of psychological factors may also elevate this risk, with anxious Type D patients being more likely to experience a ventricular arrhythmia during the first year following implantation.<sup>9</sup> The latter study found no main effect for depression, anxiety, or Type D personality.<sup>9</sup> Type D personality typifies individuals who experience increased negative emotions, such as worrying and feeling depressed, in combination with not sharing such negative emotions with others due to fear of their reaction and ultimate rejection.<sup>9</sup>

Studies examining the role of psychological factors as risk factors for mortality in ICD patients are scarce, despite factors such as depression,<sup>10,11</sup> anxiety,<sup>12,13</sup> and Type D personality<sup>14–16</sup> being associated with increased risk of mortality in patients with both coronary artery disease (CAD) and heart failure. To our knowledge, only three studies have examined the role of psychological factors as determinants of mortality in patients treated with ICD therapy, with these studies demonstrating an increased risk associated with the psychosocial status of the patient.<sup>17–19</sup>

The objective of the current study was to examine the influence of Type D personality and ICD patient concerns at the time of implantation on mortality in a cohort of consecutively implanted ICD patients.

## Methods

### Patients and study design

The study cohort consisted of consecutive patients who received a first-time ICD ( $N = 371$ ; 79.5% men; mean age =  $57.7 \pm 12.0$  years) between August 2003 and December 2008 at the Erasmus Medical Center, Rotterdam, The Netherlands. All patients were enrolled in the Mood and personality as precipitants of arrhythmia in patients with an Implantable cardioverter Defibrillator: A prospective Study (MIDAS). Patients with a life expectancy of  $<1$  year, on the waiting list for heart transplantation, with a history of psychiatric illness other than affective/anxiety disorders, or with insufficient knowledge of the Dutch language were excluded from the study. The MIDAS study was approved by the medical ethics committee of the Erasmus Medical Center. The study was conducted according to the ethical guidelines of the Helsinki Declaration, as set out by the World Medical Association. All patients provided written informed consent.

### Procedure

An ICD nurse approached all patients for participation in the study and asked them to complete a set of standardized and validated psychological questionnaires at baseline (i.e. 1 day prior to ICD implantation). Information on demographic and clinical characteristics were also gathered at baseline; information on demographics, smoking status, and prescription of psychotropic medication were either assessed by means of purpose-designed questions in the baseline questionnaire or derived from the patients' medical records. Information on clinical variables was obtained from the patients' medical records.

### Measures

#### Baseline demographic and clinical variables

Demographic variables included gender, age, marital status, and education. Information on clinical variables included indication for ICD therapy (primary vs. secondary), cardiac resynchronization therapy, QRS  $> 120$  ms, left ventricular ejection fraction (LVEF), CAD, previous myocardial infarction (MI), previous percutaneous coronary

intervention, previous coronary artery bypass graft surgery, heart failure, atrial fibrillation, diabetes mellitus, smoking, cardiac (i.e. amiodarone,  $\beta$ -blockers, diuretics, angiotensin-converting enzyme inhibitors, statins, and digoxin) and psychotropic medication.

### Psychological assessments

#### Type D personality

Type D personality was assessed with the 14-item Type D Scale (DS14),<sup>20</sup> which was administered at baseline. The DS14 assesses two personality traits, namely negative affectivity (e.g. 'I often feel unhappy'; seven items) and social inhibition (e.g. 'I am a closed kind of person'; seven items). Items are answered on a five-point Likert scale ranging from 0 (false) to 4 (true), with a score range from 0 to 28 for both subscales.<sup>20</sup> Patients with a Type D personality are typified by a high score on both negative affectivity and social inhibition, as determined by a standardized cut-off  $\geq 10$  on both subscales.<sup>20,21</sup> The DS14 is a valid and reliable measure, with a good internal consistency, as shown by Cronbach's  $\alpha$  of 0.88/0.86 and 3-month test-retest reliability of  $r = 0.72/0.82$  for the negative affectivity and social inhibition subscales, respectively.<sup>20</sup> The DS14 was originally developed in cardiac patients and identifies patients with a high risk for morbidity and mortality, independent of standard risk factors and mood states, such as anxiety and depression.<sup>22</sup> It is the combination of the two traits, negative affectivity and social inhibition rather than the single traits that incurs an increased risk of poor prognosis.<sup>15</sup> The DS14 has shown to be a stable measure during an 18-month period in post-MI patients<sup>23</sup> and to be unconfounded by indicators of somatic disease, including left ventricular (LV) dysfunction, and measures of anxiety and depression.<sup>23,24</sup>

#### Pre-implantation device-related concerns

The eight-item ICD Patient Concerns questionnaire (ICDC) was administered at baseline to assess device-related concerns as reported by the patient.<sup>25</sup> The ICDC was originally developed in the UK<sup>26</sup> and later adapted and abbreviated for the Dutch setting.<sup>25</sup> Patients rate the items (e.g. 'I am worried about my ICD firing' and 'I am worried about symptoms/pain associated with my ICD firing') on a five-point Likert scale from 0 (not at all) to 4 (very much so). All items are summed together in a total score (score range from 0 to 32), with a higher score indicating more device-related concerns.<sup>25</sup> As there is no standardized cut-off for the ICDC, we divided patients into a high vs. low concern group, using the highest tertile (cut-off  $\geq 13$ ) to indicate a high level of concerns. The internal consistency of the eight-item ICDC is good, as demonstrated by a Cronbach's  $\alpha = 0.91$ .<sup>25</sup>

### Delivered implantable cardioverter defibrillator therapy during follow-up

Recording of delivered ICD therapy started from the time of ICD implantation. All patients were followed at 3-month intervals and were advised to contact our outpatient clinic following a symptomatic event as soon as possible. Two experienced electrophysiologists from the electrophysiology staff of the Erasmus Medical Center reviewed and categorized all spontaneous episodes with stored electrograms that resulted in ventricular therapies. If the two reviewers disagreed about the stored electrograms, a third reviewer was consulted and a consensus was reached. For each episode, the date, type, and mean cycle length of the tachyarrhythmia, and the type and outcome of delivered ICD therapy were recorded. The arrhythmias were classified as (i) ventricular tachyarrhythmia or (ii) atrial tachyarrhythmia without a coexistent ventricular arrhythmia. Therapy triggered by ventricular tachyarrhythmias was considered appropriate, whereas therapy delivered for atrial tachyarrhythmias (including atrial fibrillation, atrial

flutter, atrial tachycardia, and sinus tachycardia) or T-wave oversensing and noise was categorized as inappropriate.

## Endpoint

The endpoint was defined as mortality (all-cause), with the mean follow-up period being  $1.7 \pm 0.5$  years (median follow-up = 2 years; range = 47 days to 2 years). No patients were lost to follow-up. Information on mortality was obtained from the patients' medical records.

## Statistical analysis

Patients who died during the follow-up period were compared with survivors using the  $\chi^2$  test (Fisher's exact test when appropriate) for nominal variables and Student's *t*-test for continuous variables. Kaplan–Meier curves were generated to compare the risk of mortality stratified by group (i.e. Type D vs. non-Type D personality and high vs. low ICD concerns). Univariable and multivariable Cox's proportional hazard regression analyses were used to examine the influence of the psychological risk markers (i.e. Type D personality and high levels of ICD concerns) and their clustering on mortality. As recommended by others,<sup>27</sup> we selected our covariates for the multivariable models a priori based on the literature and decided to adjust for sex, age, ICD indication, aetiology, and shocks (appropriate or inappropriate) during the follow-up period. For the results of the Cox proportional hazard models, hazard ratios (HRs) and their corresponding 95% confidence intervals (CIs) are reported. All data were analysed using SPSS 17.0 for Windows (SPSS Inc., Chicago, IL, USA). All tests were two-tailed, and a *P*-value of  $<0.05$  was used to indicate statistical significance.

## Results

### Participants vs. non-participants on baseline characteristics

Of 391 patients implanted with an ICD, 20 (5.1%) patients either refused to participate in the study or did not have sufficient data on either the Type D Scale or the ICDC to calculate a valid score on the questionnaire. Hence, analyses were based on 371 patients. The 20 patients excluded from analyses were more likely to have a history of atrial fibrillation (55.0 vs. 23.2%;  $P = 0.003$ ) and to have had a recent MI (30.0% vs. 6.2%;  $P = 0.002$ ), but less likely to be prescribed diuretics (30.0% vs. 56.1%;  $P = 0.04$ ), compared with the 371 patients included in the analyses. No other statistically significant differences were found between the two groups on demographic and clinical baseline characteristics.

### Patient baseline characteristics

Patient baseline characteristics for the total sample and stratified by survival status are shown in Table 1. During follow-up, 25 of 371 (6.7%) patients died. Patients who died during the follow-up period were more likely to be older, to have CAD, a previous MI, a Type D personality, score high on ICD concerns, and to experience more ICD shocks (both appropriate and inappropriate) during follow-up (all  $P$ s  $< 0.05$ ). No other statistically significant differences were found between the two groups on demographic and clinical baseline characteristics, including cardiac and psychotropic medication.

Type D and non-Type D patients, and patients with high vs. low levels of pre-implantation ICD concerns, did not differ systematically on the majority of demographic and clinical characteristics. The only exceptions were that Type D patients were less likely to have a partner (12.0 vs. 4.9%;  $P = 0.04$ ) and more likely to take psychotropic medication (26.5 vs. 14.3%;  $P = 0.015$ ) than non-Type D patients. Patients with high levels of pre-implantation ICD concerns were less likely to have heart failure (31.5 vs. 43.4%;  $P = 0.034$ ) and more likely to take psychotropic medication (24.6 vs. 13.2%;  $P = 0.009$ ) than patients with low levels of pre-implantation ICD concerns. The length of follow-up did not differ significantly between Type D and non-Type D patients ( $603 \pm 196$  vs.  $606 \pm 194$  days;  $P = 0.91$ ), nor between patients with high vs. low levels of pre-implantation ICD concerns ( $616 \pm 185$  vs.  $599 \pm 199$  days;  $P = 0.42$ ). Similarly, the number of patients receiving a shock (both appropriate and inappropriate) during the follow-up period did not differ between Type D and non-Type D patients (19.3% vs. 18.8%;  $P = 1.00$ ), nor between patients with high vs. low pre-implantation ICD concerns (19.7% vs. 18.4%;  $P = 0.88$ ).

### Type D personality, pre-implantation implantable cardioverter defibrillator concerns, and survival

Of all patients, 22.4% had a Type D personality and 34.2% had high levels of ICD concerns. At follow-up, the incidence of mortality was higher in patients with a Type D personality (13.3% vs. 4.9%; HR: 2.74; 95% CI: 1.24–6.03;  $P = 0.01$ ) and high ICD concerns (11.0% vs. 4.5%; HR: 2.38; 95% CI: 1.08–5.23;  $P = 0.03$ ). Kaplan–Meier curves for the time to mortality stratified by Type D personality and high levels of ICD concerns are shown in Figure 1. The unadjusted HRs associated with the respective psychological factors are reported above the Kaplan–Meier curves.

In multivariable analysis, Type D personality (HR: 2.79; 95% CI: 1.25–6.21;  $P = 0.01$ ) remained an independent predictor of mortality, adjusted for gender, age, ICD indication, CAD, and shock (both appropriate and inappropriate) during the follow-up period (Table 2). Any ICD shock during follow-up was also associated with an increased risk of mortality at follow-up (HR: 3.00; 95% CI: 1.31–6.88;  $P = 0.01$ ). Similarly, in adjusted analysis, high levels of pre-implantation ICD concerns were associated with a more than two-fold increased risk for mortality (HR: 2.38; 95% CI: 1.06–5.34;  $P = 0.04$ ) (Table 2). Shock during follow-up was again associated with poor survival (HR: 2.92; 95% CI: 1.29–6.59;  $P = 0.01$ ).

### Clustering of psychological risk markers

Given that both Type D personality and high levels of pre-implantation ICD concerns were independently associated with mortality, in secondary analysis, we examined the influence of the clustering of these two psychological risk markers in individual patients on mortality. As shown in Figure 2, the incidence of mortality was significantly higher in patients with both Type D personality and high pre-implantation concerns (18.2% vs. 5.2%;  $P = 0.005$ ). The risk for mortality in patients with the clustering of these two risk markers remained both statistically significant and

**Table 1** Patient baseline characteristics for the total sample and stratified by mortality a median of 2 years post-implantation

Characteristics	Total (N = 371)	Dead (n = 25)	Alive (n = 346)	P-value
Demographics				
Women	76 (20.5%)	5 (20.0%)	71 (20.5%)	1.00
Age (mean $\pm$ SD)	57.7 $\pm$ 12.0	63.3 $\pm$ 10.6	57.3 $\pm$ 12.1	0.02
Single/no partner	24 (6.5%)	2 (8.0%)	22 (6.4%)	0.67
Lower education <sup>a</sup>	215 (58.9%)	18 (72.0%)	197 (57.9%)	0.24
Clinical				
Primary prevention indication	237 (63.9%)	12 (48.0%)	225 (65.0%)	0.14
CRT	105 (28.3%)	11 (44.0%)	94 (27.2%)	0.12
Shocks during follow-up <sup>b</sup>	70 (18.9%)	11 (44.0%)	59 (17.1%)	0.002
QRS > 120 ms	192 (51.8%)	18 (72.0%)	174 (50.3%)	0.06
LVEF $\leq$ 35% <sup>c</sup>	274 (87.0%)	18 (90.0%)	256 (86.8%)	1.00
CAD	216 (58.2%)	20 (80.0%)	196 (56.6%)	0.04
Previous MI	186 (50.1%)	19 (76.0%)	167 (48.3%)	0.02
Previous PCI	93 (25.1%)	9 (36.0%)	84 (24.3%)	0.29
Previous CABG	76 (20.5%)	7 (28.0%)	69 (20.0%)	0.48
Heart failure	146 (39.4%)	14 (56.0%)	132 (38.2%)	0.12
Atrial fibrillation	86 (23.2%)	7 (28.0%)	79 (22.8%)	0.73
Diabetes	55 (14.9%)	7 (28.0%)	48 (14.0%)	0.08
Smoking	43 (11.6%)	0 (0.0%)	43 (12.5%)	0.10
Medication				
Amiodarone	70 (18.9%)	7 (28.0%)	63 (18.2%)	0.35
$\beta$ -blockers	293 (79.0%)	20 (80.0%)	273 (78.9%)	1.00
Diuretics	208 (56.1%)	18 (72.0%)	190 (54.9%)	0.15
ACE-inhibitors	260 (70.1%)	18 (72.0%)	242 (69.9%)	1.00
Statins	210 (56.6%)	14 (56.0%)	196 (56.6%)	1.00
Digoxin	60 (16.2%)	5 (20.0%)	55 (15.9%)	0.80
Psychotropic medication	63 (17.1%)	5 (20.0%)	58 (16.9%)	0.78
Psychological				
Type D personality	83 (22.4%)	11 (44.0%)	72 (20.8%)	0.02
Pre-implantation ICD concerns <sup>d</sup>	127 (34.2%)	14 (56.0%)	113 (32.7%)	0.03

Results are presented as *n* (%) unless otherwise indicated. CABG, coronary artery bypass graft surgery; CAD, coronary artery disease; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PCI, percutaneous coronary intervention.

<sup>a</sup>Less than or equal to 13 years.

<sup>b</sup>Appropriate or inappropriate shocks.

<sup>c</sup>Information on assessment of left ventricular function, either by means of echocardiography, nuclear imaging, or angiography was available for 84.9% (315/371) of the patients.

<sup>d</sup>Cut-off  $\geq$  13 on the ICD Concerns questionnaire.

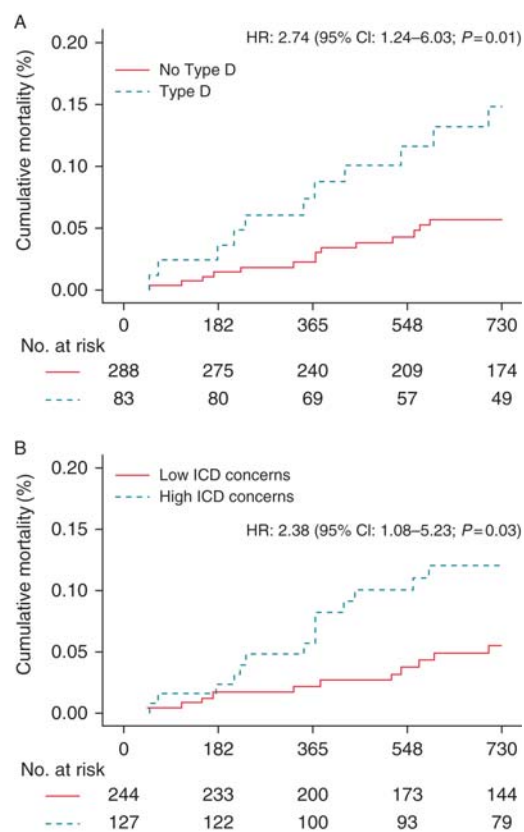
clinically relevant, with the risk being close to four-fold (HR: 3.86; 95% CI: 1.64–9.10;  $P = 0.002$ ), adjusting for gender, age, ICD indication, CAD, and shock (both appropriate and inappropriate) during the follow-up period. The occurrence of any ICD shock during the follow-up period was also an independent predictor of mortality (HR: 3.09; 95% CI: 1.36–7.04;  $P = 0.007$ ).

## Discussion

The objective of the current study was to examine the influence of Type D personality and pre-implantation device-related concerns on mortality in a cohort of consecutively implanted ICD patients. We found that the psychological profile of the patient both had a statistically significant but also a clinically relevant impact on short-term survival, despite state-of-the-art treatment with ICD

therapy. The risk of poor prognosis was enhanced by two-fold in patients with high levels of pre-implantation concerns or a distressed personality, whereas the risk in patients with clustering of *both* psychological risk markers increased to close to four-fold compared with patients with only one or none of these markers. The risk associated with the psychological factors was independent of any ICD shock during follow-up, ICD indication, CAD, gender, and age. To our knowledge, to date, only three studies in ICD patients have examined whether psychological factors and patient-reported quality of life impact on survival.<sup>17–19</sup> Two of these studies were subanalyses of the second Multicenter Automatic Defibrillator Implantation Trial (MADIT II)<sup>19</sup> and the Antiarrhythmics Versus Implantable Defibrillators (AVID) trial.<sup>18</sup> Both studies confirmed an impact of patient-reported quality of life and the patient's psychosocial status on survival. In a prospective





**Figure 1** Kaplan-Meier curves for the time to mortality stratified by (A) Type D personality and (B) high levels of ICD concerns.

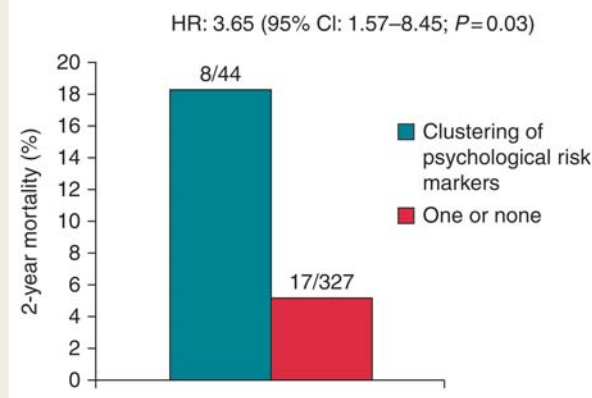
**Table 2** Type D personality, high levels of pre-implantation ICD concerns, and survival (adjusted analysis)

	HR	95% CI	P-value
Type D personality			
Type D personality	2.79	1.25–6.21	0.01
Male sex	0.58	0.21–1.61	0.29
Age	1.03	0.99–1.71	0.20
Primary prevention indication	0.75	0.32–1.74	0.50
CAD	2.31	0.80–6.69	0.12
Shock during follow-up <sup>a</sup>	3.00	1.31–6.88	0.01
High levels of pre-implantation ICD concerns			
Pre-implantation ICD concerns <sup>b</sup>	2.38	1.06–5.34	0.04
Male sex	0.71	0.25–1.99	0.51
Age	1.04	1.00–1.09	0.08
Primary prevention indication	0.84	0.37–1.91	0.67
CAD	1.99	0.69–5.74	0.20
Shock during follow-up <sup>a</sup>	2.92	1.29–6.59	0.01

Cox's proportional hazard regression analysis. CAD, coronary artery disease.

<sup>a</sup>Appropriate or inappropriate shocks

<sup>b</sup>Cut-off  $\geq 13$  on the ICD Concerns questionnaire.



**Figure 2** Mortality stratified by the clustering of psychological risk markers (i.e. Type D personality and high levels of ICD concerns). Total numbers are listed on top of bars.

cohort study of ICD patients, Ladwig *et al.*<sup>17</sup> demonstrated that the development of post-traumatic stress in ICD patients also has an impact on survival.

Previously, studies in patients with acute coronary syndrome and heart failure have indicated that Type D personality is associated with a two- to four-fold increased risk of mortality independent of traditional risk factors and indicators of disease severity, including LV dysfunction and New York Heart Association (NYHA) functional class.<sup>14–16</sup> A recently published study demonstrated that Type D personality also increases the risk of adverse clinical outcome in patients treated with ICD therapy.<sup>9</sup> In the latter study, anxious patients with a Type D personality (i.e. patients with both a Type D personality and high levels of anxiety) had a higher risk for ventricular arrhythmia. The results of the current study extend these findings, by showing that Type D, and the clustering of pre-implantation ICD concerns and Type D, is also related to poorer survival. Rozanski *et al.*<sup>28</sup> has previously emphasised the importance of studying the influence of clustering of psychosocial risk factors, as the tendency is to study single risk factors, which is less likely to capture the real risk factor burden to individual patients.

In the current study, we also found that shock during the follow-up period was associated with increased risk for mortality. This finding concurs with the results of subanalyses of the MADIT-II and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), which have also demonstrated that shock may be associated with poor survival.<sup>29,30</sup> As shown in SCD-HeFT by Poole *et al.*,<sup>29</sup> the association between ICD shocks and survival may in part be attributed to the progression of heart failure, but their results also showed that inappropriate ICD shocks were associated with an increased risk of mortality.

Given that psychological factors impact on survival in patients treated with ICD therapy and carry unique predictive value above and beyond standard biomedical risk factors, as demonstrated here and in other studies,<sup>17–19</sup> it is important to assess and monitor the psychological status of patients in clinical practice. Paradoxically, these factors are not assessed standardly, nor can a proxy be derived from traditional biomedical factors routinely

assessed. Hence, they need to be assessed in their own right in order to optimise the clinical care of ICD patients.

Brief, standardised and validated, disease-specific measures are available that have been developed specifically to tap symptoms important to ICD patients, such as the 8-item ICD Patient Concerns questionnaire<sup>25</sup> used in the current study, the 10-item Florida Shock Anxiety Scale,<sup>31</sup> and the 18-item Florida Patient Acceptance Survey.<sup>32,33</sup> One of these measures could easily be used as a screening tool in clinical practice, as it comprises little burden to patients. Moreover, the physician or the ICD nurse could use such assessment to discuss more sensitive psychological issues with patients and their families, which may be particularly welcome. Importantly, there is evidence to show that ICD patients derive benefit from psychological and behavioural intervention in terms of reductions in distress,<sup>34–36</sup> which in turn may improve the quality of life and survival. In other words, we do have something to offer to ICD patients who are at higher risk for adverse clinical outcome based on their psychological profile, if we would only identify this subset of patients in clinical practice.

This study has some limitations. First, the number of clinical events at follow-up was limited. This reduced the number of covariates that we could enter in multivariable analysis, as over-fitting statistical models reduces the power of the study and renders models unstable.<sup>27</sup> Hence, we also did not include partner status, heart failure, and psychotropic medication, although Type D/non-Type D patients did differ on partner status and the use of psychotropic medication, and patients with high vs. low levels of pre-implantation ICD concerns on the presence of heart failure and psychotropic medication. However, neither partner status, nor heart failure, nor psychotropic medication was related to mortality in univariable analysis (data not shown). Secondly, we were not able to adjust statistically in multivariable analysis for LV dysfunction, due to missing information on LV dysfunction in 56 (15.1%) patients. However, there was no statistically significant difference in the proportion of patients with an LVEF of  $\leq 35\%$  experiencing an event during follow-up vs. event-free patients. Thirdly, we did not have information about the cause of death, but only about general survival status and the time of death. Fourthly, we only examined the impact of Type D personality and high levels of pre-implantation concerns on short-term outcome. In future studies, it will be important to investigate whether these effects are also present on the long term, although evidence from Type D research indicates that to be the case in other cardiac populations, such as acute coronary syndrome, heart failure, and patients with peripheral arterial disease.<sup>22,37</sup>

In conclusion, both Type D personality and high pre-implantation ICD concerns increased the risk for mortality post-implantation independent of traditional biomedical risk factors and ICD shock. The risk of poor prognosis was further enhanced if these two psychological risk markers clustered together within individual patients, with the associated risk increasing from two-fold to close to four-fold. This finding indicates that in patients receiving ICDs, the psychological profile of the patient carries unique predictive value. This subgroup of high-risk patients should be identified and monitored in clinical practice and would likely benefit from a combined distress management programme and cardiac rehabilitation.<sup>35</sup>

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